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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,436	08/01/2003	Michael F. Thomashow	21835-00004	3828
27144	7590	05/01/2007	EXAMINER	
FOSTER, SWIFT, COLLINS & SMITH, P.C. 313 SOUTH WASHINGTON SQUARE LANSING, MI 48933			KUMAR, VINOD	
ART UNIT		PAPER NUMBER		
		1638		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/632,436	THOMASHOW ET AL.
	Examiner	Art Unit
	Vinod Kumar	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/6/07.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9, 11, 12, 17 and 20-25 is/are pending in the application.
 - 4a) Of the above claim(s) 9, 11 and 17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12 and 20-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 August 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Objections and Rejections

1. Office acknowledges the receipt of Applicant's request for continued examination (RCE) filed in the paper of 02/26/2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 9, 11-12, 17, and 20-25 are pending. Claims 12 and 20-25 are examined in the instant Office action. All previous claim objections and rejections not set forth below have been withdrawn in view of claim amendments.

Election/Restriction

2. Claims 9, 11 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 30, 2005. The restriction was made final in the Office actions mailed on 10/17/2006.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

3. Claims 12 and 20-24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim 12 contains NEW subject matter ("95%") which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed on 10/17/2006. Applicants traverse the rejection in the paper filed on 02/26/2007.

Applicants argue that the claims originally filed clearly establish that the Applicants contemplated any amount of homology greater than 85%. As 95% is greater than 85% (i.e. 95% is at least 85%) that range is clearly within the teaching of the specification. Applicants cite *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ, 97 (CCPA 1976) to support their arguments.

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that the specification does not provide written description support for sequences that are at least 95% homologous to SEQ ID NO: 1. Applicant's attention is specifically drawn to *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ, 97 (CCPA 1976), wherein court concluded as follows:

[i]]n the context of this invention, in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants' invention.

It should be noted that *In re Wertheim* specification cited a range of 25% to 60% and further exemplified processes using 36% and 50% solids. In the instant case Applicants have failed to exemplify a method for regulating cold and dehydration regulatory genes in a plant using sequences having identity within the range of 85% to 100% of SEQ ID NO: 1. One skilled in the art would not know that 95% sequence identity to SEQ ID NO: 1 was a part of the invention. Thus, the requirements set forth by court (*In re Wertheim*) have not been satisfied. Accordingly, the rejection is maintained.

Claims 12 and 20-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Claim 12 recite "exposing said plant to cold or drought stress so that transcription regulating protein in that plant is expressed" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for the claimed method in which SEQ ID NO: 1 would be expressed only after treating with drought or cold stress. For example, SEQ ID NO: 1 operably linked to a non-inducible promoter would not require drought/cold stress treatment. This does not comply with written description requirements. In the paper filed on 02/26/2007, Applicants refer to paragraph 167 of specification supports the specific step recited in the amended claim. It is noted that paragraph 167 of specification provides the support for transgenic plants

expressing SEQ ID NO: 1 under the inducible promoter (e.g. cold or drought inducible).

The amended claim reads on expressing SEQ ID NO: 1 under any promoter which includes a non-inducible and constitutive promoter. A non-inducible constitutive promoter would not require the method step of exposing plants to cold or drought stress so that SEQ ID NO: 1 is expressed. The specification does not support the amended method step as recited in the claim 12.

Accordingly, claims 12, and 20-25 are rejected.

Claim Rejections - 35 USC § 112

4. Claims 12, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 and claims dependent thereon, are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 12 is missing the essential step of expressing the dehydration regulatory genes. The last step only results in a plant expressing cold or drought regulatory gene. In claim 12, preamble recites "A method for regulating cold and dehydration regulatory genes", however, line 6 of claim recites "drought regulatory gene is expressed". Paragraph 0038 of specification refers dehydration stress to drought, high salinity and other conditions, which cause a decrease in cellular water potential in plant. It is unclear why only drought gene would be expressed, when the method is directed to regulate dehydration regulatory genes. It is unclear what is intended?

Claim Rejections - 35 USC § 102

5. Claims 12, and 20-25 remain rejected under 35 U.S.C. 102(e) as being anticipated by Harper et al. (United States Patent Publication 2002/0160378; filed August 24, 2001) taken with the evidence of Kagaya et al. (Nucleic Acids Research, 27:470-478, 1999) for the reasons of record stated in the Office actions mailed on 03/21/06, 07/27/06 and 10/17/06, and further taken with the evidence of Thomashow et al. (US Paten Publication No. US2004/0078852).

It is maintained that Harper et al. disclose a transgenic plant and a method of producing said plant comprising transforming a plant cell or plant with a DNA expression cassette comprising a promoter (constitutive, inducible or tissue-specific) operably linked to a coding sequence of SEQ ID NO: 2316 (encoding a DNA binding protein RAV1) which has 100% sequence identity to instant SEQ ID NO: 1. The reference further discloses that over-expression of SEQ ID NO: 2316 induces stress tolerance in said transgenic plant, and wherein said stress includes freezing, drought and other types of environmental stresses. Furthermore, reference also discloses method steps of selecting or screening transgenic plants comprising SEQ ID NO: 2316 with improved abiotic stress tolerance for cold or dehydration. See in particular, page 2, paragraph 0012 and 0017; page 3, paragraph 0020; page 7; paragraph 0039; page 12, paragraph 0067; page 13, paragraph 0079; page 18, paragraph 0109. Also see in particular, page 5, paragraph 0031, page 10, paragraph 0054. Also see claims 29, 33, 35, 46, 47, 49, 51, 52, 53 and 55.

Furthermore, Harper et al. also disclose plant cells or tissues susceptible to infection with *Agrobacterium tumefaciens* that contain and express a chimeric gene comprising a promoter operably linked to SEQ ID No: 2316 which has 100% sequence identity to instant SEQ ID NO: 1. See page 24 and paragraph 0145.

The property of binding to a CAACA sequence is inherent to the sequence taught by Harper et al., as evidenced by Kagaya et al. (page 478, first and second paragraph).

It must be noted that the property of regulating cold and dehydration genes in a plant is inherent to Harper et al's method comprising expressing SEQ ID NO: 2316 (100% identity to instant SEQ ID NO: 1) encoding a transcription regulating protein in a transgenic plant. This inherent property is further evidenced by Thomashow et al. who disclose a method for regulating cold and dehydration regulatory genes in a plant comprising expressing a nucleotide sequence which has 100% identity to instant SEQ ID NO: 1.

In the paper filed on 02/26/07, Applicants argue that Harper et al. SEQ ID NO: 2316 is identified in Table 7 as being a saline stress responsive sequence. Applicants further argue that Harper et al. do not teach that transgenic plants expressing SEQ ID NO: 2316 have cold or drought tolerance (response, page 5, lines 16-21).

As discussed in detail in previous Office actions that property of cold or drought tolerance is inherent to the method disclosed in Harper et al. which clearly disclose a method of making a stress tolerant transgenic plant and selecting said transgenic plants on an abiotic stress, such as cold, dehydration (includes salt, drought etc). These

inherent properties of SEQ ID NO: 1 are further evidenced by Thomashow et al. as discussed above.

Also see *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates"). Furthermore, see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, the rejection is maintained.

Summary

6. Claims 12, and 20-25 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER
4/11/07